OCT 7 - 2004

Attachment 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K042458.

1. Submitter's Identification:

A.M. Surgical, Inc
290 East Main Street
Suite 200
Smithtown, NY 11787
Tel: 631-979-9777
Fax: 631-980-4369

Date Summary Prepared: September 9, 2004

2. Name of the Device:

a. Proprietary: A.M. Surgical CPF Distal Radial External Cross Pin Fixation System
b. Common Name: Multiple Component Metallic External Bone Fixation Appliance
c. Classification Name: Appliance, Fixation, Nail, Blade, Plate Combination Multiple Component, Metal Composite
d. Device Class: 21 CFR 888.3030, Class II
e. Classification Panel: Orthopedic
f. Product Code: 87 LXT

3. Predicate Device Information:

The A.M. Surgical Distal Radial External Cross Pin Fixation System is substantially equivalent in intended use and design to the NBX-Non Bridging External Fixator marketed by Biomet Orthopedics, Inc. under K020905.

4. Device Description:

A.M. Surgical CPF Distal Radial External Cross Pin Fixation System is an external wrist fixator made of titanium , consisting of two (distal and proximal) connecting slide sections with predetermined angled holes. Standard Kirschner wires (K-wire) are inserted through the predetermined angle holes for fracture fixation, three on the distal section and two on the proximal section. The sections can be adjusted distal to proximal and locked into place by way of a center hex screw.

The device will be offered sterile and is single use.

5. **Intended Use:**

The A.M. Surgical CPF Distal Radial External Cross Pin Fixation System is to be used for external stabilization of open and/or unstable fractures of the distal radius were soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of external fixation.

6. **Comparison to Predicate Devices:**

The A.M. Surgical CPF Distal Radial External Cross Pin Fixation System is identical to the predicate in intended use, and similar in design in that both devices include an external frame on pin or k-wire implants. The device differ in that the predicate is used off the fracture site, while the subject device is used through the fracture site.

7. **Conclusions:**

The A.M. Surgical CPF Distal Radial External Cross Pin Fixation System is substantially equivalent to the predicate and is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

A.M. Surgical, Inc.
C/o Ms. Carolann Kotula
mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K042458
Trade/Device Name: A.M. Surgical CPF Distal Radial External Cross Pin Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: September 9, 2004
Received: September 13, 2004

Dear Ms. Kotula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use

510(k) Number (if known):

Device Name: A.M. Surgical CPF Distal Radial External Cross Pin Fixation System

Indications For Use:

The A.M. Surgical CPF Distal Radial External Cross Pin Fixation System is to be used for external stabilization of open and/or unstable fractures of the distal radius were soft tissue injury may preclude the use of other fracture treatments such as IM roding, casting, and other means of external fixation.

Prescription Use X AND/OR -Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042458